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PATENT CASE: **OC01128K**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Houghton, et al

For Patent: **COMBINATION THERAPY FOR CANCER**

Serial No.: 09/768,445

Filed: January 24, 2001

Examiner: (to be assigned)

Group Art Unit: (to be assigned)

Schering-Plough Corporation
Kenilworth, New Jersey 07033

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. § 1.56, Applicant hereby discloses the following information for consideration by the Examiner:

Foreign Patent Documents

1. WO 97 07804 A

Other Documents

2. Kano, Y, et al., "Effects of CPT-11 in Combination with Other Anti-Cancer Agents in Culture" INTERNATIONAL JOURNAL OF CANCER, US, New York, NY vol. 50, no. 4, 20 February 1992 (1992-02-20), pages 604-610, XP000563779 ISSN: 0020-7136, Page 606, left-hand column, line 21 – page 609, right-hand column.

3. Eder, JP et al., "Sequence effect of irinotecan (CPT-11) and topoisomerase II inhibitors in vivo" CANCER CHEMOTHERAPY AND PHARMACOLOGY, DE, Springer Verlag, Berlin, vol 42,

no. 4, 1998, pages 327-335, XP00211007, ISSN: 0344-5704, Abstract.

4. Plowman, J. et al., "Preclinical Antitumor Acitiviy of Temozolomide in Mice: Efficacy Against Human Brain Tumor Xenografts and Synergism with 1,3-Bis (2-Chloroethyl)-1-Nitrosurea" Cancer Research, US, American Association for Cancer Research, Baltimore MD, vol. 54, no. 14, 1994, pages 3793-3799, XP000914803 ISSN: 0008-5472, page 3795, right-hand column, line 21 – page 3798, right-hand column, line 4.

5. Newlands, E.S. et al., "Temozolomide: A Review of Its Discovery, Chemical Properties, Pre-Clinical Development and Clinical Trials" CANCER TREATMENT REVIEWS, US, Saunders, vol. 23, no. 1, 1997, pages 35-61, XP000921344, ISSN: 0305-7372, page 46, line 20 – page 48, line 19.

6. Vikas J. Patel, et al., "Schedule-dependent Activity of Temozolomide plus CPT-11 against a Human Central Nervous System Tumor-derived Xenograft[1]",CLINICAL CANCER RESEARCH, Vol. 6, (2000), Pages 4154-4157.

7. Peter J. Houghton, et al., "Antitumor Activity of Temozolomide Combined with Irinotecan Is Partly Independent of O^6-Methylguanine-DNA Methyltransferase And Mismatch Repair Phenotypes in Xenograft Models[1]", CLINICAL CANCER RESEARCH, Vol. 6, (2000), Pages 4110-4118.

Copies of these documents and a PTO-1449 Form are enclosed. The Examiner is kindly requested to initial and return the PTO-1449 Form to evidence consideration of these references.

Some of the above references were cited in the international counterpart to the above-identified case in a PCT International Search Report mailed on May 5, 2001. A copy of the Search Report is also enclosed.

As per 37 CFR 1.97, because the IDS is being filed prior to the mailing of a first office action on the merits, applicants respectfully request consideration of the IDS by the Examiner.

Respectfully submitted,

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I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, D.C. 20231
ON 6/22/01

WILLIAM LEE
(REGISTERED REPRESENTATIVE)

6/22/01
(SIGNATURE AND DATE)

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.: OC01128K	SERIAL NO.: 09/768,445
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT: Houghton, et al.	
(Use several sheets if necessary)	FILING DATE: January 24, 2001	GROUP:

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES	TRANSLATION NO
	AL	WO 97 07804 A						
	AM							
	AN							
	AO							

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	AP	Kano, Y., et al., "Effects of CPT-11 in Combination with Other Anti-Cancer Agents in Culture" February 2, 1992, International Journal of Cancer, Vol. 50, No. 4, pgs. 604-610
	AQ	Eder, JP et al., "Sequence effect of irinotecan (CPT-11) and topoisomerase II inhibitors in vivo", 1998, Cancer Chemother. Pharmacol., Vol. 42, No. 4, pgs. 327-335
	AR	Plowman, J., et al., "Preclinical Antitumor Activity of Temozolomide in Mice: Efficacy Against Human Brain Tumor Xenografts and Synergism with 1,3-Bis (2-Chloroethyl)-1- Nitrosurea", 1994, Cancer Research, Vol. 54, No. 14, pgs. 3793-3799
	AS	Newlands, E.S., et al., "Temozolomide: A review of its Discovery, Chemical Properties, Pre-Clinical Development and Clinical Trials", 1997, Cancer Treatment Reviews, Vol. 23, No. 1, pgs. 35-61
	AT	Vikas J. Patel, et al., "Schedule-dependent Activity of Temozolomide plus CPT-11 against a Human Central Nervous System Tumor-derived Xenograft[1]", 2000, Clinical Cancer Research, Vol. 6, pgs. 4154-4157
	AU	Peter J. Houghton, et al., "Antitumor Activity of Temozolomide Combined with Irinotecan is Partly Independent of O^6-Methylguanine-DNA Methyltransferase and Mismatch Repair Phenotypes in Xenograft Models[1]", 2000, Clinical Cancer Research, Vol. 6, pgs. 4110-4118

EXAMINER	DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.